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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,312	06/12/2001	Laurie H. Glimcher	HUI-027CPDV	6498

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,312

Applicant(s)

GLIMCHER ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-60 is/are pending in the application.
- 4a) Of the above claim(s) 30,33,55 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 31, 32, 34-54 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/086,010, filed May 27, 1998, now US patent 6,274,338, which is a continuation in part of 09/030,579, filed February 24, 1998, now abandoned.

As indicated in the transmittal letter filed June, 12, 2001, page 2, the specification has been amended to indicate the priority information. Claims 29-60 are pending.

Election/Restrictions

Applicant's election without traverse of Group I is acknowledged. Claims 29-60 are pending. Claims 55 and 56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse. In addition, Applicants elect species (3), a cell containing a c-Maf reporter gene construct, as the means used in the method to assay compounds that modulate c-Maf expression. Claims 30 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Claims 29, 31, 32, 34-54 and 57-60 are currently under examination as they are drawn to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Specification

The disclosure is objected to because of the following informalities:

On page 1, line 6, the grant information has been omitted and left blank. On page 1, lines 10-14, incorrect related application information is present. It is noted that the priority information has been inserted as requested in Applicants' transmittal papers, however there was no amendment to delete the old information.

Appropriate correction is required.

Claims

Claims 29, 31, 32, 34-54 and 57-60 are objected to because of the following informalities: it is noted that the elected species is a method wherein a cell with a reporter construct is used to assay c-Maf activity. The claims should be amended to reflect the elected species. As Applicants have indicated (see Applicants election page 2, last line of the page), it is noted that additional species would be searched once the elected species has been found allowable, however the elected species is not free of the art, therefore other species will not be searched.

Appropriate correction is required.

Priority

This application is a Continuation-In-Part of application 09/030,579 with new matter introduced into Figures 1 and 2 (also Seq ID NO 1 and 2). Applicant has inserted sequence information not previously present in the parent application. For figure 1, the applicant has

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insert nucleotides 515 to 720 previously represented as Ns in the parent application, and for figure 2, the applicant has inserted the corresponding new amino acids 172 to 240 previously reported as Ns. This portion of the sequence will be considered new matter, and as such will have the priority date reflected by the filing date of this application, 09/086,010 (filing date May 27, 1998).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 31, 32, 34-54 and 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 57 are vague and unclear because the effect being assayed and analyzed is not clearly set forth. The claims vaguely set forth the use of compositions, however what is comprised in the composition is not clearly set forth, nor is any specific effect that should be observed, nor is any correlative step for interpreting the effect once observed. It is unclear if the method is practiced in vitro with an isolated cell or in vivo, and if in vivo, how a construct was provided and how it will be used in the assay. It is noted that Applicants have elected the species of a cell with a reporter construct, however how this is comprised in the claimed composition is insufficiently set forth in the instant claim. Dependent claims set forth specific cell types and reporter transgenes, however these fail to clearly defined the assay being performed and fail to define the metes and bounds of how the assayed is practiced. With respect to claim 57, it is

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noted that a cytokine is assayed, however there is no clear correlation with the effect of the compound on the cytokine and the effect on c-Maf. Because a cytokine amount or activity goes up or down in response to the administration of a compound is insufficient to determine that the compound had an affect on c-Maf. The claim is incomplete because critical steps that provide a nexus between any cytokine and c-Maf activity is not adequately set forth. Finally, the claims require the use of 'human c-maf', however c-maf is part of a large family of proteins obtainable from a variety of mammalian species each sharing a significant homology. No specific sequence is set forth in the instant claims, and it is unclear exactly what c-maf protein is being used, how modified in can/could be, or what uniquely defines a sequence as human. It is unclear if the claims encompass the use of a fragment of a c-maf obtained from a non-human source that shares 100% homology with a c-maf obtained from a human cDNA or if such a sequence is excluded or how the artisan could even differentiate these two sequences. More specifically setting forth the SEQ ID of the c-maf being used in the assay would obviate this portion of the rejection.

Claim 32 is incomplete because it does not have active steps for practicing the method as claimed. The claim is vague and unclear because what compound is being tested and what affects are being assayed are not clearly set forth in the claim, nor the specification. Further, the claim is drawn to a new method and does not further limit claim 29 because there is no specific modulation of c-Maf in claim 29 that indicates what compound should be used in the method set forth in claim 32.

Claim 37 is vague and unclear because the location of the endogenous promoter and the structural or functional metes and bounds of the promoter sequence being used is not clearly set

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forth. The claim is indefinite because the sequences required to practice the claimed method are not adequately defined.

Claim 40 and 41 vague and unclear because the sequence from which “-157 to +58” is derived not defined, nor is its context within the construct being used. The interleukin gene has been described and thus exists in several species of mammals, however neither the claim nor the specification adequately define the sequences encompassed by the instant claim. Similarly, claim 41 is unclear in where the sequence ends or begins to adequately define where one would obtain ‘about 3kb’ of upstream sequence.

Claims 43-47 are unclear in the recitation of ‘derived from’ because how similar or different a resulting cell should be from the cell from which it is ‘derived’ is not adequately set forth. More clearly indicating that the cell comprising the reporter construct is a particular cell line or cell type would obviate the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 31, 32, 34, 35, 37-49, 51-54, 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodge *et al.* (Mol Cell Biol, 1995).

Hodge *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on IL-4 expression (figure 5) and reporter genes such as CAT (figure 4). The cell types used in the assays include B cell M12B lymphoma and nonlymphoid HEPG2 cells. Because Hodge *et al.* teach a cell based reporter assay method for assaying immune response as related to IL-4 and other reporter genes as it is related to the presence of c-Maf, the methods of Hodge *et al.* anticipates the instant claims.

Claims 29, 31, 34, 40, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kataoka *et al.* (Mol Cell Biol, 1995).

Kataoka *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on the reporter activity of luciferase (see figure 9). Because Kataoka *et al.* teach a cell based reporter assay method for assaying a reporter gene as it is related to the presence of c-Maf, the methods of Kataoka *et al.* anticipates the instant claims.

Claims 29, 31, 34, 37, 40, 42, 43, 48 and 50 are rejected under 35 U.S.C. 102(a) as being anticipated by Hedge *et al.* (Mol Cell Biol, 1995).

Hedge *et al.* teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on the reporter activity of a reporter gene or in the context of a two hybrid system (see figures 1-3 and Table I). The affects of the different transcriptional factors

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are put in the context of differentiation of myeloid cells, thus are directly relevant to affects and modulation of the immune system (see discussion pages 2735-36). Because Hedges *et al.* teach a cell based reporter assay method for assaying a reporter gene as it is related to the presence of c-Maf, the methods of Hedges *et al.* anticipates the instant claims.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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